

REMARKS

Upon entry of the claim amendments made herein claims 1-8 are pending. Applicants have amended claim 1, herein. No new matter has been added.

The 35 U.S.C. § 112 rejections

Written Description

The Examiner has rejected claims 1-8, on page 2 of the Office Action, under 35 U.S.C. § 112, first paragraph, for lack of written description. Applicants have amended claim 1, herein. Applicants submit that claims 1-8 have sufficient written description in light of this amendment and request that this rejection be withdrawn.

The 35 U.S.C. § 102 rejection

The Examiner has rejected claims 1, 2, 3, 7 and 8, on page 5 of the Office Action, under 35 U.S.C. § 102, for being anticipated by Briend *et al.* U.S. Patent No. 5,670,177 ("Briend"). The Examiner asserted that Briend teaches the administration of mixtures of nitric oxide and carbon dioxide blood-flow to abdominal organ decrease preventing agent. Applicants have amended claim 1, herein, to stipulate that the blood-flow to abdominal organ decrease preventing agent is not nitric oxide. Briend does not teach this limitation. Thus, Applicants request that this rejection be withdrawn.

The 35 U.S.C. § 103 rejection

The Examiner has rejected claims 4-6, on pages 5-6 of the Office Action, under 35 U.S.C. § 103, for obviousness over Briend in light of Stamler *et al.* U.S. Patent No. 6,314,956 ("Stamler"). The Examiner argued that while Briend differs from the invention of claims 4-6 in the use of ethyl nitrite as opposed to nitric oxide (NO), one of ordinary skill in the art would expect ethyl nitrite to have the same activity as NO based on the teaching in Stamler that ethyl nitrite is an NO donor. Applicants respectfully disagree.

Stamler teaches that the administration of ethyl nitrite, while being an NO donor, has much different effects from the administration of NO. Stamler teaches that the pulmonary administration of NO causes the reaction of NO with oxygen or reactive oxygen species to create

NO₂ or other toxic NO_x.¹ This toxicity is manifested in inflammation, airway hyperreactivity, hemorrhage or delay in clinical improvement.² Ethyl nitrite avoids the toxicity associated with NO use.³

A person having ordinary skill in the art would not consider NO and ethyl nitrite to be equivalent. Ethyl nitrite does not act in the same or a similar way as NO, as explained above. Thus, one of ordinary skill in the art would not expect ethyl nitrite and NO to act equivalently. Thus, the teachings of Stamler teach away from the teachings of Briend because the ethyl nitrite in Stamler is taught not to be equivalent to the NO in Briend.

Because of the lack of equivalency between NO and ethyl nitrite, the Examiner has not shown a *prima facie* case of obviousness with the rejection of claims 4-6 in light of Briend over Stamler. In order to form a *prima facie* case of obviousness, the prior art may only be modified or combined to reject claims if there is a reasonable expectation of success.⁴ Obviousness does not require absolute predictability, however, at least some degree of predictability is required.⁵ While, the ethyl nitrite in Stamler is used to treat the same indications as NO, a person having ordinary skill in the art would not have had a reasonable expectation of success to adopt ethyl nitrite to the methods of Briend. Stamler teaches, as explained above, that ethyl nitrite has much different effects when administered to a patient than NO. Thus, one of ordinary skill in the art would not expect NO and ethyl nitrite to have the same effect on a patient when administered for the treatment of a distinct pathology.

For the above reasons, Applicants request that the rejection of claims 4-6 for obviousness, be withdrawn.

¹ See Stamler at column 1, lines 20-21.

² *Id.* at lines 22-24.

³ *Id.* at lines 51-55.

⁴ MPEP § 2143.02.

⁵ *Id.*

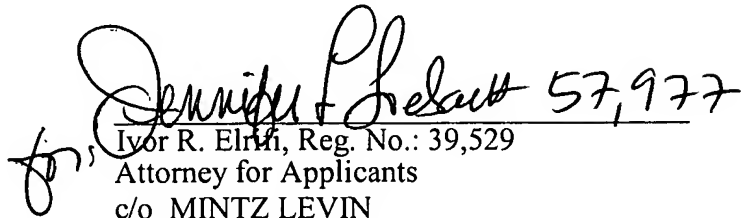
U.S.S.N.: 10/714,980
Applicant: Stamler

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Dated: July 21, 2006


Ivor R. Elrhi, Reg. No.: 39,529
Attorney for Applicants
c/o MINTZ LEVIN
Tel: (617) 542-6000
Fax: (617) 542-2241
Customer No. 30623

TRA 2178692v.1